

ent by: SIMPSON WOOLLEY MC CONACHIE, L.L.P.

**SIMPSON WOOLLEY
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ATTORNEYS AT LAW**

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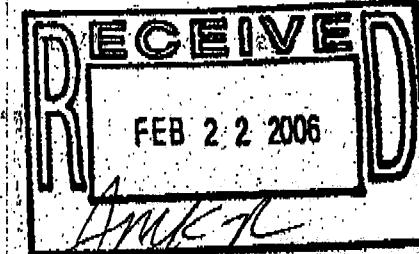
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TOTAL NUMBER OF PAGES: 2 (PLUS THIS COVER PAGE)

DATE: February 22, 2006

FILE NUMBER: Citizen Petition of Terry Fredeking and Antibody Systems, Inc.

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**SIMPSON WOOLLEY
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February 22, 2006

Via Facsimile 301 827 0440 and US Mail

Jesse Goldman, MD, MPH
Director, Center for Biologics Evaluation
and Research
Food and Drug Administration (HFM-1)
5630 Fischers Lane
Rockville, Maryland 20857

Re: Citizen Petition 2005-0182/CP1

Dear Dr. Goldman:

On May 13, 2005 the captioned Citizen's Petition was filed by the agency. On or about October 28, 2005, we received a response from your office to the effect that despite the 180-day deadline there was no response to the Citizen's Petition. Under 21 CFR 10.30(e)(2) such an interim response should contain a statement as to why the response was delayed. The letter dated October 28th did not comply with 21 CFR 10.30(e)(2)(iii). Subsequently, I wrote stating the interim response was not a proper one.

Another 100 plus days have now passed with no announcement of any action on the captioned Citizen's Petition.

The failure of the agency to follow its own regulations in the timely processing of Citizen's Petitions is leaving our client no choice but to seek a declaration from the appropriate federal district court that FDA has not followed its regulations on both the handling of the Citizen's Petition and the substantive issue raised in the Citizen's Petition—the issuance of a Warning Letter that did not follow FDA law and regulation.

In an attempt to reach a final conclusion without having to undertake litigation I request that the Petition be granted or denied on or before March 15, 2006. Absent such an action, the agency will have denied due process with regard to the legal right to petition the agency and force this matter to litigation.

ent. By: SIMPSON WOOLLEY McCONACHIE LLP

February 22, 2006

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SIMPSON WOOLLEY McCONACHIE LLP

Sincerely,

Charles R. McConachie

Charles R. McConachie

CC Antibody Systems, Inc.

Feb-22-2006

SIMPSON WOOLLEY McCONACHIE LLP

Charles R. McConachie

Charles R. McConachie